

November 16, 2015

Barbara Lee, Director California Department of Toxic Substances Control 1001 I Street P.O. Box 806 Sacramento, California 95812-0806

Submitted via: CALSAFER.DTSC.CA.GOV

RE: Comments Submitted by Gradient on Behalf of the Halogenated Solvents Industry Alliance (HSIA) on Draft Stage 1 AA Guide

Dear Director Lee:

We are writing on behalf of the members of the Halogenated Solvents Industry Alliance (HSIA) to provide input on DTSC's recently released draft Stage 1 Alternative Analysis Guide for the California Safer Consumer Products (SCP) program. We appreciate the opportunity to provide the following comments and look forward to the Agency's response.

General Comments

Generally, the SCP Stage 1 Alternative Analysis (AA) Guide does not provide the detail necessary to understand how an AA under the program should actually be conducted. Instead the document makes reference to procedures developed by other groups that the Guide acknowledges will not fully address the SCP requirements. Although the Guide suggests that the SCP regulations give the responding entity the details of how to prepare the AA (page 9), the regulations themselves lack specifics; they indicate what concerns must be addressed but not how they should be addressed. Thus more detail in the Guide is necessary. Lacking such detail, DTSC is asking responsible parties to devote considerable time and effort in developing an analysis without any certainty that it will be acceptable to the Agency. This is an unreasonable expectation.

Product Performance

Adequate performance is a critical requirement for any alternative and must be the first factor considered. It makes little sense to investigate a lower hazard alternative if it cannot perform the required function in the product. The SCP regulations acknowledge that performance requirements not only have to be identified in Stage 1 but also that identified alternatives must meet these requirements (SCP Regulations § 69505.5 (b)(1)(A)). Despite the crucial importance of performance evaluation, the Guide is inconsistent on how performance and function are addressed as part of Stage 1. Contrast, for example, the Table on page 16, and Chapter 2 page 24-26 with Chapter 3 Table 3-1. We also note that in the recent BizNGO report on alternatives to methylene chloride in paint strippers, performance requirements were only identified but not used to evaluate alternatives (DTSC identifies BizNGO tools as a resource in the Guide). We suggest that Stage 1 consider availability and performance using readily available data and qualitative metrics; Stage 2 should involve a more detailed and quantitative consideration of these factors. This is the typical approach used in other AA frameworks and should be acceptable to DTSC.

The guide provides very little information about where the responsible entity can obtain data on product performance, cost, availability, and feasibility. Data on hazard and exposure are relatively easy to obtain as long as chemical identity (e.g., CAS number) is known. Even where such data are not available, modeling and surrogate methods can be used to fill data gaps. However, such tools are not available for addressing lack of data on performance, cost, availability and feasibility. For the Guide to be a successful

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tool for responsible parties, it should describe ways in which these likely data issues can be addressed. The Guide currently focuses mostly on data sources for hazard and exposure information. This is helpful but not sufficient.

We further suggest that the Guide direct readers to the ECHA guidance on preparation of applications for authorization under REACh, specifically pages 46-62. This document has more detail than the Guide concerning the evaluation of availability of alternatives and performance (referred to as technical feasibility) and provides a number of reasonable examples of how different performance criteria might be considered.

Life Cycle Thinking

Multiple times in the document, DTSC refers to consideration of product life cycle. We request that DTSC include a discussion of the differences between life cycle thinking (LCT) and life cycle analysis (LCA), and indicate that a full LCA is not required. The SCP regulations (§ 69505.6) are not clear on this point so clarification in the Guide is appropriate. We note that many of the examples DTSC uses to illustrate life cycle issues are fairly simplistic, considering only a few alternatives or only a few life cycle concerns. An example of what DTSC expects that is more realistic of what responsible parties will encounter would be helpful. We do find the simple table DTSC supplied in the 2nd AA Guide webinar (slide 25) to be helpful. Is completing this table indicative of the level of life cycle consideration required for Stage 1? These points aside, we expect that many responsible entities may encounter great difficulty in obtaining reliable life cycle data (*e.g.*, energy use, CO₂ emissions, natural resource depletion). Such data are available for major commodity materials (*e.g.*, steel, cement, petroleum fuels) but this may not be true for the specialty chemicals which will be the focus of the SCP regulation. DTSC should identify sources where life cycle data for these types of materials can be obtained.

Scope of Analysis

On page 30, DTSC notes that a responsible entity need not consider an alternative that is not "a feasible alternative to its manufacturing business model." The Agency should provide specific examples beyond the fairly simple one provided. Scoping is a critical element of an AA and it is essential for the responsible entity to understand the breadth of analysis that must be undertaken. Increasing the breadth of alternatives under study (e.g., from different flame retardants that may be used in polyurethane furniture cushions to a consideration of possible flame retardants in different seating materials [wood, metal, solid plastic, wool, horsehair upholstery, bean bags, etc.]) dramatically increases the amount and difficulty of data collection and also complicates comparison of alternatives. We agree with DTSC that a manufacturer should not be required to include an alternative that is incompatible with its existing business model and which is outside its area of technical expertise.

Iteration

In both the Guide and the two webinars, DTSC repeatedly discusses the iterative nature of the AA process. We agree that revisiting assumptions and choices made at discrete points in the process is advisable, e.g.., between Stages 1 and 2 and at the end of the selection process as part of an uncertainty analysis. However, the Guide seems to imply that multiple iterations within a Stage are encouraged (although this is not stated clearly). This seems counterintuitive to the two stage process, which is meant to streamline the analysis and make it more efficient. Repeatedly revisiting decisions made may lead to endless analysis and prevent one from reaching a clear conclusion. We request that DTSC further explain the level of iteration in the AA process that is desired. Providing clear and relevant examples would be most helpful.

Economic Impacts

Perhaps the most novel element of the SCP regulations is the requirement that responsible entities undertake something akin to a regulatory impact analysis (RIA) to estimate the costs of the current chemical and the alternatives. No other AA framework we have reviewed contains such a potentially burdensome requirement. In particular, the requirement for the responsible party to enumerate costs to government agencies and NGOs (presumably health care costs, waste management costs, pollution cleanup costs, *etc.*) is unprecedented. It is also unclear where the responsible entity is supposed to obtain the data necessary to support this analysis. We recognize that this topic will be addressed in the Stage 2 guidance and is only referenced in Stage 1 as part of the overview discussion. We request that in the Stage 2 draft, DTSC provide detailed guidance and suggestions on how this AA requirement can be addressed.

Different Tools/Different Results

In the Guide DTSC identifies a number of hazard evaluation tools that Responsible Entities may use to identify and assess the hazards of different alternatives (Guide p. 57). As DTSC acknowledges, even the most comprehensive of these tools do not address all of the SCP hazard endpoints, limiting their value to a Responsible Entity which will have to create a novel framework for incorporating all the relevant SCP hazard endpoints. This leaves the Responsible Entity with considerable uncertainty as to whether their hazard evaluation framework will be acceptable. Prior to actually imposing AA requirements, DTSC should develop an exemplary hazard identification tool which can address all of the specified SCP hazard endpoints.

Different hazard evaluation tools cited by DTSC may also yield different results. For example, GreenScreen and USEPA's DfE Safer Chemical Ingredients List (SCIL) lead to different conclusions about the suitability of specific chemicals, a fact highlighted in the recent BizNGO report on alternatives to methylene chloride in paint strippers. Both GreenScreen and DfE are identified as potential tools in the Guide. How does DTSC expect Responsible Entities to reconcile such differences? DTSC states that the Guide will be used by DTSC staff as a tool for reviewing submitted AAs. DTSC should clarify that the choice of which hazard identification tool to use is at the discretion of the Responsible Entity.

Data gaps

It seems clear that responsible entities will not be able to obtain all the data needed to fully evaluate the chemical of concern and possible alternatives, and that data gaps are inevitable. The Guide is inconsistent with regard to the extent to which data gaps need to be addressed. For example, DTSC suggests that data gaps should be filled using models or analog data (p. 51), but elsewhere notes that the regulations do not require responsible entities to fill data gaps (p. 56). DTSC needs to clarify what is expected concerning data gaps. Again, specific examples of when filling a data gap is advisable and when it is not would be helpful.

We request that DTSC consider the points noted above in finalizing the AA Guide, which will be a critical document for responsible entities seeking to comply with the SCP requirements. We appreciate the opportunity to provide input on this important element of the SCP development process.

Sincerely,

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